AUG 3 0 2002

510 (k) Summary

Trade Name	Andersen® Nasogastric Tube with Stylet (AN 11S, 13S, 14S and 18S)
Manufacturer	Andersen Products, Inc. 3202 Caroline Drive Haw River, NC 27258
Device Generic Name	Nasogastric tube
Classification	Nasogastric tubes have been classified as Class II. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for gastrointestinal tubes.
Predicate Device	Andersen® Nasogastric Tube with Stylet (AN 10S), K935688
Device Description	Sterile, disposable, bilumenal, medical grade vinyl nasogastric tube with radiopaque vent tube, 24 round aspirating ports, and anti-reflux filter. Includes a lubricated polyethylene stylet. The tubes are marked to aid in positioning the tube during passage.
Indications for Use	The Andersen® Nasogastric Tube is indicated in those situations where the physician desires to keep the stomach continuously and completely evacuated of swallowed air, swallowed saliva, gastric secretions or fresh blood in a fasting patient for a prolonged period, such as pancreatitis, cholecyctitis, post-operative ileus and non-operative management of peptic ulcer. It is also indicated to keep the stomach evacuated of fresh blood once clots have been removed.
Safety and Performance	No new risks were added by the modification. In support of this Special 510(k), Andersen Products, Inc. has provided a declaration of conformity to 21 CFR § 820.30 Design Control requirements.
Conclusion	Based on the indications for use and comparison to its predicate device, the Andersen® Nasogastric Tube with Stylet has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2002

Ms. Wendy Hedrick
Director
Quality Assurance/Regulatory Affairs
Andersen Products, Inc.
Health Science Park
3202 Caroline Drive
HAW RIVER NC 27258

Re: K021493
Trade/Device Name: Andersen Nasogastric Tube with Stylet (AN 11S, 13S, 14S and 18S)
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: July 29, 2002
Received: July 31, 2002

Dear Ms. Hedrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K021493

Device Name Andersen® Nasogastric Tube with Stylet (AN 11S, 13S, 14S and 18S)

Indications for Use The Andersen® Nasogastric Tube is indicated in those situations where the physician desires to keep the stomach continuously and completely evacuated of swallowed air, swallowed saliva, gastric secretions or fresh blood in a fasting patient for a prolonged period, such as pancreatitis, cholecyctitis, post-operative ileus and non-operative management of peptic ulcer. It is also indicated to keep the stomach evacuated of fresh blood once clots have been removed.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR § 801. 109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021493